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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/884,877 06/20/2001 Henricus Petrus Joseph Te Riele 065691-0230 3654 22428 7590 04/10/2006 **EXAMINER** FOLEY AND LARDNER LLP WOITACH, JOSEPH T SUITE 500 ART UNIT PAPER NUMBER 3000 K STREET NW WASHINGTON, DC 20007 1632

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/884,877	TE RIELE ET AL
	Examiner	Art Unit
	Joseph T. Woitach	1632
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status Status		
1) Responsive to communication(s) filed on 18 January 2006.		
2a) This action is <b>FINAL</b> . 2b) This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is		
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
4)⊠ Claim(s) <u>33-49</u> is/are pending in the application.		
4a) Of the above claim(s) <u>34-49</u> is/are withdrawn from consideration.		
5) Claim(s) is/are allowed.		
6) Claim(s) is/are rejected.		
7)⊠ Claim(s) <u>33</u> is/are objected to.		
8) Claim(s) are subject to restriction and/or election requirement.		
Application Papers		
9)⊠ The specification is objected to by the Examiner.		
10)⊠ The drawing(s) filed on <u>June 20, 2001</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.		
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).		
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).		
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. § 119		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>		
Attachment(s)		
1) Notice of References Cited (PTO-892)	4) Interview Summary	
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	atent Application (PTO-152)

#### **DETAILED ACTION**

This application filed June 20, 2001 is a continuation in part of 09/147,712, filed February 23, 1999, now abandoned, which is a national stage filing of PCT/EP95/02980, filed July 26, 1995.

Applicants amendment filed January 18, 2006, has been received and entered. Claim 33 has been amended. Claims 1-32 have been canceled. Claims 33-49 are pending.

#### Election/Restriction

Applicant's election with traverse of Group I, in Paper No. 13 was acknowledged. No new arguments are provided in Applicants' instant amendment, Therefore, the requirement is maintained for the reasons of record and still deemed proper.

It is noted that the examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.1 16; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

Claims 33-49 are pending. Claims 34-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13. Claims 24, 27, 28 and 33 are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### Claim Objections

Claim 33 is objected to because of the following informalities:

The evidence of record indicates that the claimed dMsh2-9 cell line has been deposited. However, neither the specification nor the claim have the appropriate deposit information. It is suggested that the claim be amended to reflect the deposit number of the deposited cell line.

Appropriate correction is required.

### Specification

The disclosure is objected to because of the following informalities:

As discussed above, the claimed cell line dMsh2-9 has been deposited, however this has been completed to conform with the requirements of 35 USC 112, first paragraph, during prosecution. It is suggested that the information regarding the particulars of the deposit be incorporated into the instant specification.

Appropriate correction is required.

### Claim Rejections - 35 USC 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claim 33 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

The evidence and declaration provided by Applicants have obviated the basis of the deposit requirement.

## Claim Rejections - 35 USC 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims previously rejected under 35 U.S.C. 103(a) as being unpatentable over Varlet et al., Genbank accession number X81143, and Berns et al. (US Patent 5,789,215 or WO 93/04169) in view of Orth et al. (PNAS, 1994) is withdrawn.

Cancellation of the claims has obviated the basis of the rejection.

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#### Conclusion

Claim 33 is objected.

This application is in condition for allowance except for the following formal matters:

Amendment of claim 33 to include the ATCC deposit number of the claimed cell line is required.

Prosecution on the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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